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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|--------------------|-------------|-----------------------|------------------|
| 08/879,469         | 06/20/97    | MURGITA               | R 06727/006001   |
|                    |             |                       | EXAMINER         |

FISH & RICHARDSON  
225 FRANKLIN STREET  
BOSTON MA 02110-2804

HM21/0331

| CLASSIFICATION | PAPER NUMBER |
|----------------|--------------|
| 1645           | 20           |

DATE MAILED: 03/31/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 6/20/97
- ☒ This action is **FINAL**.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-19 + 21-24 is/are pending in the application.
- Of the above, claim(s) 1-18 + 22-24 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 19 + 21 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1645

### Part III DETAILED ACTION

#### *Response to Amendment*

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.
2. In response to Applicants' Amendment B (Paper No. 12), filed on 10/7/96, claim 20 has been cancelled. Claims 19 and 21 have been amended. Claims 1-19 and 21-24 are pending in the instant Application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's Amendment C (Paper No. 19), filed 6/20/97, has also been entered.
3. A provisional election was made by voice-mail message by Karen F. Lech on 2/9/96 without traverse to prosecute the invention of Group I, claims 19-21. **Affirmation of this election must be made by applicant in responding to this Office action.** Claims 1-18 and 22-24 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.
4. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
5. Claims 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention for reasons of record and the following. Applicant's arguments filed 10/7/96 have been fully considered but they are only partly persuasive. The Examiner withdraws his first ground of rejection concerning the applicability of the in vitro results for in vivo uses. However, the enablement rejection is maintained for failure to teach the skilled artisan how to use the claimed method of administration of human  $\alpha$ -fetoprotein to a mammal in order to stimulate bone marrow cell proliferation because there is no adequate written description, guidance, or examples by which the harmful effects of the administration can be avoided without undue experimentation for reasons of record. As stated in a previous Office Action (Paper No. 7, filed 4/4/96, page 5), the dosage guidance disclosed is over a range of one hundred billion. This range is too large and does not enable the skilled artisan to practice the invention with a reasonable expectation of success because of the suppressive effects of human  $\alpha$ -fetoprotein on cells of the immune system (see Paper No. 7, pages 6-7). The Examiner respectfully disagrees with Applicant that a working example of administration to a mammal has been provided in the specification (see Paper No. 11, page 7), therefore the instant situation cannot be distinguished in this manner from In re Colianni, 195 USPQ 150, CAFC. Furthermore, when administered to a mammal, the human  $\alpha$ -fetoprotein will encounter not only immature bone marrow cells, but also the fully-differentiated mature T-cells in the bloodstream, so Applicant's argument that an "apples and oranges" comparison has been made is not persuasive because both cell types will be encountered, and the skilled artisan would have no means of predicting how to administer, how much to administer, and how long to

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administer human  $\alpha$ -fetoprotein to a mammal to produce the desired results without incurring the known deleterious effects without engaging in undue experimentation.

6. Claims 19 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoskin et al. for reasons of record and the following. Applicant's arguments filed 10/7/96 have been fully considered but they are not persuasive. The instant specification does not disclose whether glycosylation plays any role in the biological activity of human  $\alpha$ -fetoprotein (AFP). The prior art is equivocal: "...the role of sialic acid in the immunological activity of AFP remains contentious. It is equally possible that the immunoregulatory function of AFP is determined by primary structure rather than by posttranslational modification" (Hoskin et al., 1985, page 164). Based upon these factors, it would appear that glycosylation of AFP is immaterial to its function, and thus AFP taught in the prior art is functionally equivalent to that of the instant specification, and so the instant methods recited in claims 19 and 21 are obvious over the prior art of record.

7. No claim is allowed.

8. This is a continuation of applicant's earlier Application No. 377,316. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Mondays through Thursdays from 0730 to 1800.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

March 16, 1998

  
PAULA K. HUTZELL  
SUPERVISORY PATENT EXAMINER